

Appl. No.: 10/767,962  
Amendment dated September 2, 2005  
Reply to Office Action of June 2, 2005

### REMARKS

Reexamination and reconsideration of this Application, withdrawal of the rejection, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the above claim amendments and remarks that follow.

Claims 1 and 36 have been amended to particularly recite the concentration ranges of the components of the active ingredient combination. Support for the amendments can be found throughout the specification, and particularly on page 7 of the specification. Claims 19-33 have been cancelled without prejudice or disclaimer, and Applicants expressly reserve the right to pursue the subject matter thereof at a later date. New claims 39-48 have been added, and support therefore can be found throughout the specification, and particularly on pages 10-16. Applicants submit that no new matter is introduced by the amendments or the new claims provided herein. Claims 1-13, 15-18, and 34-48 are pending in the present application.

Claims 1-13, 15-18, and 34-36 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office argues the specification does not support claim language reciting "creatine salts, and creatine esters." Applicants respectfully traverse this rejection.

Applicants respectfully direct the Office to MPEP 2163(II)(A)(3)(a)(i), which states that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics. As further provided in this section, case law clearly points out that description of a representative number of species does not require specificity on the order of individual support for each species embraced by the genus. Rather, disclosure of only a few species can be sufficient to meet the written description requirement under 35 U.S.C. §112 (particularly see *in re Rasmussen*, 650 F.2d 1212, at 1214 (CCPA 1981), where only a single species was adequate to support a genus).

The present specification, at page 7, provides a structural formula for creatine, and plainly states that the invention encompasses creatine derivatives. At page 8, the specification illustrates a specific creatine salt, creatine phosphate, showing substitution of an amino hydrogen with the salt-forming group. Page 8 further discloses additional inorganic salts (*e.g.*, creatine

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sulfate), as well as organic salts (*e.g.*, creatine acetate and creatine ascorbate). The Office argues that the disclosure of "only four compounds" does not "embrace the broad subgenus."

Seemingly, the Office attempts to place some undisclosed, arbitrary lower limit on the number of species necessary to describe a genus in accordance with 35 U.S.C. §112, first paragraph.

Applicant respectfully submits this is improper.

MPEP 2163(II)(A)(3)(a)(i) states that satisfactory disclosure depends upon whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the genus members in view of the species disclosed. The realm of creatine salts is not so broad and variable that one of skill in the art, viewing the present application, would reasonably believe anything other than that Applicants, in light of the disclosure described above, fully possessed and envisioned the group of creatine salts at the time of filing of the present application. The specification illustrates creatine itself, illustrates the structural difference relating to a specific creatine salt, and provides yet further representative creatine salts. Such description clearly envisions further creatine salts without requiring an exhaustive listing of all possible creatine salts. Accordingly, Applicants respectfully submit the specification fully complies with the written description requirement for supporting the claimed group of creatine salts.

Such is similarly the case with creatine esters. Page 8 of the specification describes creatine derivatives wherein creatine is esterified on its lone carboxyl group. The specification further describes particular embodiments wherein the creatine is esterified with mono- or polyfunctional alcohols. One of skill in the art would clearly recognize that formation of additional creatine esters would be only a matter of simple chemical modification well within the average level of skill in the art, and that the specification clearly encompasses such further esters. Furthermore, the Office has provided no evidence that one of skill in the art would reasonably believe the present written description is insufficient to support the claimed group of creatine esters. Therefore, Applicants respectfully request reconsideration and withdrawal of the present rejection.

Claims 1-11, 17-18, and 36-38 stand rejected under 35 U.S.C. §102(b) as anticipated by, or, in the alternative, under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,968,544.

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Claims 12-13, 15-16, and 34 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the '544 patent. Applicant respectfully traverses the above rejections.

The Office alleges the '544 patent teaches a composition that contains creatine, and the Office argues the composition would inherently include creatinine as it is a converted related compound of creatine that would be formed in the body. In the alternative, the Office argues the claimed composition is obvious in light of the creatine-containing composition disclosed in the '544 patent, allegedly based upon the inherent presence of creatinine converted from creatine in the body. Applicants respectfully submit the Office has failed to recognize the shortcomings of the '544 patent as a reference in the present matter.

The presently amended claims recite a cosmetic or dermatological preparation comprising a content of an active ingredient combination comprising 0.01 to 15 wt% of at least one compound selected from the group consisting of creatinine and derivatives thereof in combination with 0.01 to 15 wt% of at least one compound selected from the group consisting of creatine, creatine salts, and creatine esters. In contrast, the '544 patent discloses an acidic, creatine-containing nutritional supplement formulated for human consumption, particularly to provide a muscle performance-enhancing effect. While the '544 patent only teaches inclusion of creatine in its nutritional supplement, the Office relies on the conversion of creatine to creatinine in aqueous solution to argue the patent discloses that its nutritional supplement further contains creatinine. The Office, however, ignores the direct teaching of the '544 patent that its nutritional supplement is designed to avoid creatinine conversion and overlooks the uncertainty in the art around conversion of creatine to creatinine.

The Merck Index (12<sup>th</sup> ed.) states that, in acidic solution, the formation of creatinine from creatine is complete. The '544 patent teaches formation of creatinine in aqueous solution is undesirable and specifically states that in its nutritional supplement, such formation is mostly avoided. Accordingly, the art seems to teach that an aqueous creatine nutritional supplement can consist of solely creatine, solely creatinine (as a conversion product), or anything in between. Such vague and uncertain teaching around creatine-containing nutritional supplements can in no way be viewed as teaching or suggesting the presently claimed invention.

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As previously noted, the presently amended claims recite a cosmetic or dermatological preparation comprising a content of an active ingredient combination comprising 0.01 to 15 wt% of at least one compound selected from the group consisting of creatinine and derivatives thereof in combination with 0.01 to 15 wt% of at least one compound selected from the group consisting of creatine, creatine salts, and creatine esters. The '544 patent in no way teaches or suggests a preparation comprising creatine and creatinine in the presently recited concentrations. Accordingly, Applicants respectfully submit the '544 patent can not be cited as anticipatory of the presently amended claims.

Furthermore, and contrary to the Office's allegation, one of skill in the art would find no teaching or motivation in the creatine-containing nutritional supplement of the '544 patent to make the presently claimed cosmetic or dermatological preparation. The Office argues one of skill in the art could arrive at the presently claimed cosmetic or dermatological preparation merely by obtaining the active ingredient in a result-effective amount through "judicious selection" and "routine optimization" based on the teaching of the '544 patent. Applicant, however, respectfully submits this is an untenable position.

The '544 patent teaches a nutritional supplement for human consumption for providing a muscle performance-enhancing effect. The presently claimed invention recites a cosmetic or dermatological preparation unrelated to muscle performance-enhancing effects. The '544 patent teaches that creatinine is useless as it "has no muscle performance-enhancing effect and is excreted from the human body as a waste product in urine" (column 2, lines 7-8). Accordingly, the '544 patent teaches compositions that are specifically prepared to avoid formation of creatinine. Based on these teachings, one of skill in the art would find no motivation to use "judicious selection" or "routine optimization" to make the presently claimed preparation.

First, the Office has failed to point to any portion of the '544 patent that would lead one of skill in the art of nutritional supplements to modify the muscle performance-enhancing sport drink of the '544 patent to make a cosmetic or dermatological preparation, or that would lead one of skill in the art of cosmetic or dermatological preparations to seek out the '544 patent and its muscle performance-enhancing sport drink as a basis for making new cosmetic or dermatological preparations. Second, the Office has failed to point to any portion of the '544 patent that would

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motivate one of skill in the art to prepare a formulation including a specific amount of both creatine and creatinine. To the contrary, the '544 patent only teaches usefulness of creatine, and it specifically teaches avoidance of creatinine. One of skill in the art can not optimize the amount of creatinine in a composition when the art relied upon teaches avoidance of creatinine. Further, even if one of skill in the art relied upon the '544 patent for preparing a creatine-containing composition that includes creatinine as a conversion product, there is no teaching in the '544 patent that would motivate the skilled artisan to optimize both the creatine and the creatinine concentration in such a way as to prepare a cosmetic or dermatological preparation. Therefore, Applicants respectfully submit the '544 patent neither teaches nor suggests the presently claimed cosmetic or dermatological preparation, and Applicants respectfully request reconsideration and withdrawal of the above rejections.

Applicants further respectfully submit that the '544 patent is unavailable as a reference in relation to newly added claims 39-48. Each of the newly added claims clearly distinguishes the cosmetic or dermatological preparation of the invention from the nutritional supplement of the '544 patent through inclusion of further components, or preparation in particular forms, that are not taught or suggested by the '544 patent, and that one of skill in the art would not view as characteristic of a nutritional supplement. Accordingly, Applicants respectfully submit that newly added claims 39-48 are both novel and non-obvious over the '544 patent.

Claim 35 stands rejected under 35 U.S.C. §103(a) as being unpatentable over the '544 patent in view of U.S. Patent No. 5,576,316. Applicants respectfully traverse this rejection.

Initially, Applicants respectfully submit the Office has failed to show proper motivation to combine the references. As noted above, the '544 patent is directed to a creatine-containing nutritional supplement formulated to provide a muscle performance-enhancing effect. The '316 patent is directed to a method for inhibiting tumor growth rate. The Office has failed to point out any portion of the '544 patent that would lead one of skill in the art to seek out the growth-inhibiting teaching of the '316 patent to modify the growth-promoting supplement of the '544 patent.

Further, even if the references are properly combinable, which Applicants do not admit, the combination still fails to teach or suggest the presently claimed invention. As previously

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noted, the '544 patent teaches creatine-containing nutritional supplements that attempt to avoid creatinine formation, and there is no teaching or suggestion provided therein that would direct one of skill in the art to the presently recited cosmetic or dermatological preparation comprising specific amounts of both creatine and creatinine. Furthermore, the Office has failed to point to any portion of the '316 patent that cures the deficiencies of the '544 patent. More particularly, the combined references neither teach nor suggest a cosmetic or dermatological preparation comprising a content of an active ingredient combination comprising 0.01 to 15 wt% of at least one compound selected from the group consisting of creatinine and derivatives thereof in combination with 0.01 to 15 wt% of at least one compound selected from the group consisting of creatine, creatine salts, and creatine esters. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection.

Claims 1-6, 8-13, 17-18, and 34-38 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,242,491 in view of U.S. Patent No. 5,883,128. Further, claims 15 and 16 also stand rejected under 35 U.S.C. §103(a) over the same combination. Applicants respectfully traverse these rejections. Applicants note that while the Office references claims 1-6, 8-13, 17-18, and 34-38 in paragraph 11 of the Office Action, the arguments provided by the Office appear to relate to claims 15 and 16, and Applicants therefore direct their comments to these claims.

The Office alleges the '491 patent discloses the use of creatine for protecting skin and further alleges the '128 patent teaches the use of creatine and creatinine as individually active ingredients in treating skin disorders. The office therefore argues the combination of the two references discloses the presently claimed preparation comprising both creatine and creatinine. Applicants respectfully submit, however, that the Office has overlooked the true teaching of the '128 patent and is relying on impermissible hindsight to combine the two patents to arrive at the presently claimed invention.

The '128 patent teaches that alpha hydroxyacids, alpha ketoacids, and related compounds are effective for treating cosmetic conditions and dermatological disorders; however, the low pH associated with such composition can be irritating to human skin. Therefore, the '128 patent teaches that such compositions can be made less irritative by inclusion of an amphoteric or

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pseudoamphoteric compound. In particular, the '128 patent teaches that inclusion of an amphoteric or pseudoamphoteric compound: (a) raises overall composition pH to reduce skin irritation; and (b) leads to formation of quadruple ionic complexes that act as buffer systems to control release of the active agent – the alpha hydroxy or keto acids (see column 3, lines 58-67). The '128 patent discloses that creatine is an exemplary amphoteric compound and creatinine is an exemplary pseudoamphoteric compound. Nowhere, however, does the '128 patent teach or suggest that creatine or creatinine, either alone or in combination, are useful as cosmetic or dermatological active components. Furthermore, nowhere does the '491 patent teach that its composition is skin irritating and would benefit from modification through addition of irritation-reducing components. Accordingly, Applicants respectfully submit that one of skill in the art would find no motivation to combine the '128 patent with the '491 patent.

Even if the '491 patent and the '128 patent are combined, one of skill in the art still would find no teaching or suggestion of the presently claimed cosmetic or dermatological preparation comprising a content of an active ingredient combination comprising 0.01 to 15 wt% of at least one compound selected from the group consisting of creatinine and derivatives thereof in combination with 0.01 to 15 wt% of at least one compound selected from the group consisting of creatine, creatine salts, and creatine esters. The '491 patent discloses only the use of creatine. One of skill in the art, viewing the '128 patent, would see that amphoteric compounds or pseudoamphoteric compounds, such as creatine and creatinine, respectively, can be used to make acidic compositions less irritative. As the composition of the '491 patent already includes creatine, though, the skilled artisan would have absolutely no motivation to modify the composition of the '491 patent by adding another irritation-reducing component, such as creatinine. This is even more particularly evident since the '491 patent provides no teaching that its composition is acidic and provides no motivation to include an irritation-reducing component.

Specifically in relation to claims 15 and 16 of the present application, the Office argues it would be merely a matter of judicious selection and routine optimization within the purview of the skilled artisan to arrive at the specific concentrations and ratios recited in the present claims. Applicants respectfully disagree. As noted above, the '128 patent merely teaches the use of creatine or creatinine as a pH-raising or complex-forming component, and not as an active, skin-

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treating component of a composition. Accordingly, the '128 patent provides no direction related to the use of creatine or creatinine as a skin active component, only as a buffering or complexing agent for alpha hydroxy or keto acids. Therefore, even if one of skill in the art combined the teaching of the '491 patent with the teaching of the '128 patent, such a combination still would not provide motivation to prepare the presently claimed composition. In particular, neither the '491 patent, nor the '128 patent, alone or in combination, provides any direction for the skilled artisan related to creatinine concentrations useful as an active component of a cosmetic or dermatological preparation or related to creatine/creatinine ratios beneficial in such a preparation where both creatine and creatinine are used as active components. The skilled artisan can not make adjustments or modifications where no basis is provided.

Accordingly, absent the use of impermissible hindsight, relying on the presently claimed invention, the Office has failed to show motivation to combine the references and has failed to show that combination of the references would lead the skilled artisan to the presently claimed invention. Applicants, therefore, respectfully request reconsideration and withdrawal of these rejections.

Claims 1-11, 18, and 36-37 stand rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C §103(a) as obvious over U.S. Patent No. 4,970,072 or Published U.S. Patent Application No. 2002/0119174 to Gardlik *et al.* in view of the Venkatappaiah *et al.* abstract. Applicants respectfully traverse this rejection.

The Office argues the '072 patent discloses the use of cow's milk in baths for beautifying and health promoting effects and further argues the Gardlik *et al.* publication discloses the use of milk and honey baths to revitalize hair. Applicants respectfully point out, however, that neither of these references includes any direct teaching that creatine or creatinine, alone or in combination, are themselves useful components for a cosmetic or dermatological preparation. More specifically, neither the '072 patent nor the Gardlik *et al.* publication teach or suggest the presently claimed cosmetic or dermatological preparation comprising a content of an active ingredient combination comprising 0.01 to 15 wt% of at least one compound selected from the group consisting of creatinine and derivatives thereof in combination with 0.01 to 15 wt% of at



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least one compound selected from the group consisting of creatine, creatine salts, and creatine esters.

The '072 patent makes note of milk baths as background for its invention, which teaches whey concentrate compositions. Nothing in the '072 patent, however, teaches that other milk components have properties useful in a bath composition. The Gardlik *et al.* publication provides even less connection between milk and the presently claimed invention. The Gardlik *et al.* publication mentions milk and honey baths only to illustrate man's long-standing desire for beautiful hair. The publication actually teaches metal complex-containing compositions. Therefore, as previously stated, neither the '072 patent nor the Gardlik *et al.* publication teach or suggest the presently claimed invention.

In relation to the Venkatappaiah *et al.* abstract, Applicants respectfully submit the Office has failed to show proper motivation to combine the abstract with either the '072 patent or the Gardlik *et al.* publication. The Venkatappaiah *et al.* abstract does nothing more than disclose one assay of the nonprotein nitrogenous constituents of milk. The assay discloses that cow milk includes the following components in mg per 100 ml: urea (11.6 mg), amino acids (4.04 mg), creatine (0.62 mg), uric acid (0.54 mg), creatinine (0.44 mg), ammonia (0.26 mg), and undetermined components (8.32 mg). The Office would therefore argue that one of skill in the art, seeing the mention in the '072 patent or the Gardlik *et al.* publication of milk baths, would seek out the Venkatappaiah *et al.* abstract and specifically pick creatine and creatinine from the listing of nonprotein nitrogenous milk components to prepare a cosmetic or dermatological composition as presently claimed. Applicants respectfully submit there is no reasonable basis for such an argument.

First, milk includes a great number of different components, and the Office has failed to point to any portion of the '072 patent or the Gardlik *et al.* publication providing any teaching or suggestion as to which component of milk may make it useful as a bath. Second, the Office has failed to point to any portion of the Venkatappaiah *et al.* abstract providing any teaching or suggestion that any of the milk components disclosed therein may be useful in a cosmetic or dermatological preparation. Third, the Venkatappaiah *et al.* abstract only discloses the nonprotein nitrogenous components of cow's milk. The Office has failed to show why one of

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skill in the art would seek out a disclosure of the nonprotein nitrogenous components of cow's milk rather than the other components. For example, cow's milk also includes fatty acids, casein, lactalbumin, lactoferrin, IgA, IgG, lysozyme, serum albumin, lactoglobulin, lactose, calcium, phosphorus, sodium, potassium, and other various components. The disclosure of the '072 patent and the Gardlik *et al.* publication could just as easily motivate one of skill in the art to seek out these other components. Accordingly, Applicant's submit the Office has failed to show proper motivation to combine the references to arrive at the presently claimed cosmetic or dermatological preparation.

Further, even if the references are properly combined, which Applicants do not admit, the combination still would not lead one of skill in the art to the presently claimed invention. As pointed out above, the '072 patent and the Gardlik *et al.* publication only broadly note the historical use of milk in a bath and provide no teaching or suggestion that a single milk component, or combination of components, is particularly useful for cosmetic or dermatological preparations. The Venkatappaiah *et al.* abstract does nothing more than list six of the numerous milk components. In fact, the milk components disclosed in the abstract account for less than 0.026% (25.82 mg/100mL) of the overall composition of cow's milk. More specifically, as disclosed in the abstract, creatine is present in cow's milk at a concentration of 0.62 mg/100 mL (0.00062%) and creatinine is present at a concentration of 0.44 mg/100 mL (0.00044%). The Office has pointed to no portion of the combined references that would lead one of skill in the art to believe that components accounting for such a small percentage of the overall composition of cow's milk would be the components making it desirable for use in a bath as disclosed in the '072 patent and the Gardlik *et al.* publication. Still further, the Office has failed to point out any reasoning that would lead the skilled artisan to combined creatine and creatinine.

Moreover, even if the references are combined according to the arguments provided by the Office, one of skill in the art would be led to prepare a composition including creatine and creatinine at concentrations of 0.00062% and 0.00044%, respectively. This clearly neither teaches nor suggests the presently amended claims, which recite a cosmetic or dermatological preparation comprising a content of an active ingredient combination comprising 0.01 to 15 wt% of at least one compound selected from the group consisting of creatinine and derivatives thereof

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in combination with 0.01 to 15 wt% of at least one compound selected from the group consisting of creatine, creatine salts, and creatine esters. Furthermore, none of the cited references, either alone or in combination, provide any teaching or suggestion that would lead one of skill in the art to modify the basic composition of cow's milk to increase both the creatine concentration and the creatinine concentration by a factor of approximately 20 to arrive at the presently claimed preparation.

Summarily, a skilled artisan armed with this combination of references would find no teaching or suggestion therein of a cosmetic or dermatological preparation comprising a content of an active ingredient combination comprising 0.01 to 15 wt% of at least one compound selected from the group consisting of creatinine and derivatives thereof in combination with 0.01 to 15 wt% of at least one compound selected from the group consisting of creatine, creatine salts, and creatine esters. The argument that this combination of references provides such a teaching or suggestion can find no basis in any reasonable analysis of the references absent the use of impermissible hindsight. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection.

Applicants respectfully submit that all claims, as now submitted, are in condition for immediate allowance. Accordingly, a Notice of Allowance is respectfully requested in due course. If any minor formalities need to be addressed, the Examiner is directed to contact the undersigned attorney by telephone to facilitate prosecution of this case.

#### **Supplemental Information Disclosure Statement**

Applicants bring to the attention of the Examiner the Supplemental Information Disclosure Statement filed August 5, 2005, in the present matter, and Applicants respectfully request that a signed copy of the PTO Form 1449 be returned with the next correspondence from the Office. Applicants particularly note that although a full-text copy of the Burke *et al.* reference (No. 40) was provided with the Supplemental IDS, the reference was not re-listed on the PTO Form 1449. Accordingly, Applicants have included herewith an unmarked copy of the first PTO Form 1449 filed January 26, 2004, and Applicants respectfully request the Examiner acknowledge receipt of the Burke *et al.* reference by initialing and returning this copy.

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It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

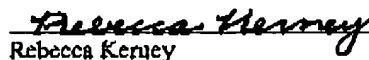
Respectfully submitted,

  
Ryan W. Cagle  
Registration No. 47,468

Customer No. 00826  
**ALSTON & BIRD LLP**  
Bank of America Plaza  
101 South Tryon Street, Suite 4000  
Charlotte, NC 28280-4000  
Tel Raleigh Office (919) 862-2200  
Fax Raleigh Office (919) 862-2260

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the US Patent and Trademark Office at Fax No. (571) 273-8300 on the date shown below.

  
Rebecca Kerney

9/2/05

Date